QUESTIONS AND ANSWERS CONCERNING INGREDIENTS

1. Why are ingredients used?

ANSWER: Some ingredients aid in processing tobacco in the initial stages of cigarette manufacture. These ingredients help in the processing of tobacco but remain in the final cigarette in minute quantities, if at all. Other ingredients are used as casing materials or humectants. Casing materials, such as sugar, help to smooth and balance the taste of cigarettes, while humectants keep the tobacco in cigarettes moist. Finally, many of the ingredients are used to give individual brands of cigarettes their distinctive flavor and aroma.

2. How long have ingredients been used in cigarettes?

ANSWER: Ingredients have been used for over 150 years. When Europeans first learned about smoking tobacco from the Indians, the tobacco they smoked was flavored with citrus peels and other spices and herbs. In the United States, the use of flavorings has been a common practice since colonial times. Most of the principal processing aids, casing materials, and humectants, for example, have not changed for decades.

3. Why are so many ingredients used?

ANSWER: To put the number of ingredients in perspective, it is worthwhile to note that there are some

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380 different brands and packings of cigarettes sold in the United States. The ingredients on the HHS list are an aggregate of all the ingredients used. Obviously not all ingredients are used in every cigarette.

Furthermore, twenty of those ingredients comprise approximately 99% of the total amount, by weight, of ingredients used in the industry. The other ingredients are used in smaller amounts, and most of the ingredients on the list submitted to HHS are used in extremely small quantities as part of flavor formulations. These formulations often include a number of ingredients, but typical industry-wide usage of many of these flavor components is under 10 pounds a year. This is in contrast with the over 850 million pounds of tobacco employed in cigarettes sold in the United States each year. The flavor formulations used by the companies change occasionally as new products are introduced or existing products are reformulated in response to consumer preferences.

4. Why are so many ingredients used in American cigarettes, when many fewer ingredients are used in cigarettes made in many other countries?

ANSWER: The very premise for this question is not true if you are talking about U.S. style cigarettes. This is because American style cigarettes are a blend of different types of tobacco, some of which call for more

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ingredients than others. Consequently, where American style blended cigarettes are the norm, there may be only slight differences in the numbers of ingredients used by manufacturers in different countries.

However, there are certain countries, such as the U.K. and its former colonies, where smokers prefer cigarettes which do not contain a blend of different types of tobacco but contain only Virginia style flue-cured tobacco. The latter do not require as many ingredients to smooth their taste as do some of the tobaccos found in blended cigarettes. Nevertheless, ingredients are used in Virginia style cigarettes as well.

5. Are ingredients used in large amounts?

ANSWER: Fewer than twenty ingredients such as casing materials (which smooth and balance the flavor of cigarettes), moisturizers, and major flavors (such as menthol), account for 99% of the weight of ingredients actually found in cigarettes. Certain ingredients that serve as processing aids are used in volume during the early stages of manufacturing but their presence is virtually eliminated in the manufacturing process. Such processing aids remain in the finished cigarette in trace quantities, if at all.

A larger number of the ingredients are used as aroma flavors to give different cigarette brands their

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distinctive aromas, but these substances are in the final cigarette in minuscule amounts. Most of the ingredients comprise these proprietary flavor mixtures, and usage of many of these ingredients by the entire industry is under 10 pounds per year.

6. Haven't the cigarette manufacturers started using more and more ingredients to compensate for the reduction of tar and nicotine in cigarettes?

ANSWER: Neither the number nor quantity of casing materials (which smooth and balance the taste of cigarettes) nor moisturizing agents have changed as a result of the growing range of tobacco products, including the introduction of lower "tar" and nicotine brands. While the number of flavors which constitute the special aromas of individual brands may have increased, it is important to note that flavors are used in minuscule amounts, the total amount of all flavors used constituting less than one tenth of one percent by weight of a finished cigarette.

7. Why hasn't the identity of ingredients been provided to the public before?

ANSWER: While the identity of the ingredients has not been provided to the public, the U.S. Government has had access to the list of all the ingredients used by the six major U.S. cigarette manufacturers.

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It is common for all companies to guard specific product formulas, and Congress recognized this when it passed the Federal Cigarette Labeling and Advertising Act. The Act requires U.S. cigarette manufacturers to submit an annual list of their ingredients but guarantees protection against disclosure of this information. The flavors added to foods, for example, are treated as trade secrets and need not be disclosed on the labels of these products.

Not only have U.S. manufacturers submitted ingredient lists each year since 1986 in full compliance with the law, but since 1979 the industry has voluntarily provided HHS with information about ingredients. Under an agreement reached in 1982, the manufacturers had provided HHS with a list of commonly-used ingredients added to tobacco in the manufacture of cigarettes. The industry agreed then to consult with HHS as it addressed any questions about specific ingredients. Consequently, the U.S. government has had access to information about ingredients for over ten years.

Because they contribute to the taste and appeal of individual brands, the identities of specific ingredients in cigarettes are also closely guarded trade secrets. Disclosure of the ingredients used in cigarette manufacture could reveal product formulas that required years of research to develop. The Federal Cigarette

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Labeling and Advertising Act recognizes the highly confidential nature of ingredients information by directing HHS to establish procedures to protect the confidentiality of the ingredients list.

8. What role did the industry have in the preparation of HHS' ingredient report?

ANSWER: We regret that the industry had no role in the preparation of the report. This strikes us as particularly unfair since as early as 1979 the industry has cooperated with HHS with respect to the ingredient issue. Well before the legislation that required that annual lists be submitted, the industry voluntarily provided information to HHS. The industry has informed HHS of its willingness to participate in a scientific review of ingredient usage.

Despite these repeated offers, the industry was offered no role in the HHS review of the ingredient lists. The industry was not consulted about the types of data that might be reviewed, and industry scientists who are perhaps the most knowledgeable persons about the use of ingredients in cigarettes were not called upon by HHS to provide information. Thus, HHS ignored a potential source of highly valuable information, and this resulted in numerous erroneous conclusions.

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are not treated as public [illegible]

often have great competitive value and require substantial time and expense to develop. The law therefore allows them to be treated as trade secrets. For example, the flavorings used in hundreds of foods and in fragrances are treated as trade secrets.

10. Why aren't the ingredients used in cigarettes listed on the package?

ANSWER: The identities of specific ingredients used in a particular brand of cigarettes are important trade secrets. The taste of a specific brand may take years of time and millions of dollars to develop, and the law recognizes that such valuable information is entitled to confidential treatment. For example, the flavors used in hundreds of foods are treated as trade secrets.

11. The list of additives which has been supplied to HHS consists of those substances which are currently added to cigarettes. Have any substances been phased out of use in cigarettes since the submission of annual lists began?

ANSWER: Yes. Like almost all consumer products, from frozen foods to breads or soft drinks, cigarettes undergo constant change as new brands are introduced and old brands are modified or phased out. Modifications in cigarette formulations may be required to compensate for

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changes in tobacco caused by variations in weather patterns, environmental conditions, agricultural practices, as well as in response to changes in consumer taste. However, most of the modifications in the composition of cigarettes affect flavors which are already in use and which are employed in extremely small quantities, less than one tenth of one percent by weight of a final cigarette. For many of these ingredients, the amount used annually is less than ten pounds for the entire industry. The major ingredients change less often, and many of them have been used for years.

12. Are there any substances currently added to cigarettes sold only in other markets, particularly Third World markets, which are not used in cigarettes sold in the United States?

ANSWER 1: The Federal Cigarette Labeling and Advertising Act only requires that information be submitted concerning ingredients used in cigarettes sold in the United States, and we have not compiled information on cigarettes sold in other countries. However, a number of other countries regulate the use of ingredients in cigarettes, and the companies comply with these regulations wherever they exist.

ANSWER 2: The Act only requires that information be submitted concerning ingredients used in cigarettes sold in the United States. However, we can assert that the cigarettes manufactured for export and sold overseas are

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identical to the comparable brands manufactured for sale in the U.S. There is no double standard. All the ingredients used in the manufacture of cigarettes are acceptable in the countries in which they are used. Indeed, many countries regulate the use of ingredients in cigarettes and we comply with these regulations.

13. Are ingredients added to filters, and if so, what ingredients are added and what tests have been done to evaluate their safety?

ANSWER: The Federal Cigarette Labeling and Advertising Act requires only that information be submitted concerning ingredients added to the tobacco used in cigarettes sold in the United States. However, we believe that the addition of ingredients to filters is not harmful to smokers.

14. Are the ingredients used in cigarettes harmful?

ANSWER: There is no legitimate basis for the conclusion that the addition to cigarettes of the ingredients on the list is harmful to smokers. Virtually all substances are toxic at very high levels, but there is no evidence that the small quantities of ingredients used in cigarettes are harmful.

15. What evidence is there that the ingredients are not harmful?

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ANSWER: Most ingredients used [illegible] manufactured in the United States are commonly used in foods, have been reviewed by the Food and Drug Administration (FDA) and are included on the FDA lists of approved food additives or substances "generally recognized as safe" (GRAS), or on the Flavor Extract Manufacturers Association's GRAS list.

Furthermore, governmental bodies in other countries, such as Great Britain and West Germany, have also evaluated ingredients used in cigarettes in those countries. The inclusion of ingredients on these lists reflects a careful review of available data by scientists. For example, the British ingredients list was developed by a medical and scientific committee appointed by the British government, the Independent Scientific Committee on Smoking and Health.

Virtually all of the ingredients used by the six leading U.S. cigarette manufacturers can be found on the accepted lists of one or more of the following governmentally affiliated or recognized organizations: the U.S. Food and Drug Administration, FEMA-GRAS, the U.K. Independent Scientific Committee on Smoking and Health (Hunter-Froggatt Committee), and the relevant government departments and agencies of Canada, Belgium, Switzerland, France and the Council of Europe.

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In view of this, we regret that the report criticizes the use of ingredients because of what it characterizes as a lack of evidence concerning adverse health effects. This statement is not accurate. The major ingredients comprise 99 percent of the total poundage of ingredients used and scientific data are available to demonstrate that the use of these ingredients in cigarettes has no adverse effects on consumers.

The tobacco industry remains committed to engaging in serious scientific discussions with responsible authorities interested in approaching the ingredients issue from a scientific perspective. We regret that HHS has not seen fit to adopt such an approach in this instance.

16. Are there any substances which have historically been used as ingredients in cigarettes that are now regarded as hazardous?

ANSWER: Cigarette manufacturers continuously review the questions that have arisen concerning ingredients. The companies believe that there is no harm to smokers from the addition to cigarettes of former or current ingredients.

17. Why is there any reason to think that an ingredient is not harmful just because it has been used for a long period of time?

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ANSWER: Cigarette manufacturers continuously review questions that have arisen concerning ingredients. The companies believe that the addition to cigarettes of ingredients formerly or currently used are not harmful to smokers. Indeed, most of the major ingredients used in large quantities in the production of cigarettes are either foods or are approved for use in foods or in the manufacture of food products.

18. What effect do ingredients have on non-smokers exposed to cigarette smoke?

ANSWER: Cigarette manufacturers continuously review questions that have arisen concerning ingredients. The companies believe that the addition to cigarettes of the ingredients on the list is not harmful to smokers. The companies likewise believe that the addition of ingredients to cigarettes is not harmful to non-smokers who may be exposed to cigarette smoke.

19. Have each of the ingredients been tested to ensure that they are not harmful?

ANSWER: Since most of the ingredients are approved for use in foods, testing to determine their toxicity has been conducted. Furthermore, the scientific literature on all ingredients has also been reviewed. This is always the first step in determining acceptability. In addition, patterns of usage of ingredients in consumer

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products have been studied. The literature and data from all the tests as well as the scientific literature demonstrate that the ingredients used are not harmful. Furthermore, the tobacco companies have conducted their own additional tests.

20. What kinds of tests have been done on ingredients?

ANSWER: The need for testing, and the types of tests to be conducted, depend on a range of factors. There are a variety of accepted testing methodologies which can be used to evaluate ingredients. Depending on the circumstances, the research conducted includes smoke chemistry, acute and chronic toxicity studies, and various in vitro studies.

21. The GRAS list and other compilations list many of these ingredients as fit for human consumption, but fail to address the issue of potential dangers posed by the burning of these substances. What research has the industry done concerning the effects of pyrolysis on these substances?

ANSWER: In order to answer this questions, it is first necessary to understand what happens when a cigarette burns. Different types of ingredients react differently when subjected to heat. Most of the ingredients that are used by the industry go into the flavoring materials used in cigarettes. These flavoring materials are sufficiently volatile that, before they get hot enough to burn, they are boiled away and transferred intact into

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industry usage of many of these flavoring ingredients is less than ten pounds a year.

For many other ingredients, overall usage levels indicate that pyrolysis data is of low priority. Indeed, only twenty or so ingredients account for approximately 99% of the total amount by weight of all ingredients used. And a number of these major ingredients are processing aids that remain in the final cigarette in trace quantities, if at all. Other ingredients which are pyrolized go into the casing materials -- which smooth and balance the taste of the cigarette -- and the humectants -- which help cigarettes retain the right moisture level.

With respect to all the ingredients used in cigarettes, whether or not they are pyrolized, the companies continuously review the scientific literature. If the literature suggests the need to test certain of these ingredients, the companies undertake appropriate testing procedures.

22. Why haven't pyrolysis tests been run for all ingredients being used?

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ANSWER. First, it is important to understand that the vast majority of ingredients in cigarettes are not pyrolyzed. They have relatively low boiling points, below the temperature of a burning cigarette, and they are transferred intact from the cigarette to the tobacco smoke. In fact, flavors are often selected for their low boiling points, which assure that their flavoring properties are imparted to cigarette smoke. Hence, for these ingredients, pyrolysis tests are not relevant.

Pyrolysis product testing on other types of ingredients is not called for in view of the manner in which they are used. Processing aids, for example, appear in the final cigarette in trace quantities, if at all. In addition, a large number of ingredients used as components of flavor mixtures are likewise found in cigarettes in minuscule quantities.

23. Are there any studies that examine the effects of the ingredients when they have been inhaled?

ANSWER: Yes. Inhalation studies on ingredients have been conducted where appropriate. The companies believe that these studies have shown that the addition to cigarettes of the ingredients tested is not harmful to smokers.

24. Have inhalation tests been conducted on all ingredients?

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ANSWER: No. Scientific convention establishes criteria for the need for various types of testing and the determination of the appropriate test based upon the available body of scientific information. To start with, the vast majority of ingredients are not pyrolyzed. They have relatively low boiling points, below the temperature of a burning cigarette, and are transferred intact from the cigarette to the tobacco smoke.

Of the remaining ingredients that are subject to pyrolysis, testing of the pyrolysis product has been undertaken in both acute and chronic bioassays. The pyrolysis product is the aggregate of all the non-tobacco materials which are burned.

With respect to the testing of individual ingredients, it has been established scientifically that laboratory pyrolysis tests of individual ingredients in isolation from each other is not appropriate since this type of testing does not accurately reflect the exposure conditions of ingredients in a burning cigarette.

25. What value is any test other than a pyroloysis or inhalation test?

ANSWER: There are a number of other tests that are accepted in the scientific and regulatory community, including the chemistry of the ingredients and chronic toxicity studies such as ingestion studies. Indeed, scientists routinely evaluate all available information

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26. Are you aware of any adverse health data generated either by the companies or available in the published literature?

ANSWER: The companies are aware of routine testing by government agencies, such as the National Toxicology Program, and in the general scientific community which evaluate the use of ingredients used in products including food and cosmetics, as well as cigarettes. While some of these studies may suggest adverse effects, based on a review of all the available data and information, the companies believe that the addition of the ingredients to cigarettes is not harmful to smokers.

27. Is more testing of ingredients planned?

ANSWER: The testing of ingredients has been conducted by individual companies on their own initiative. Companies will continue to conduct tests where they believe such tests are warranted, as well as monitor independent research findings.

28. You have noted that various bodies such as FEMA or FDA have approved the ingredients for use in foods. Why does that matter, since those organizations have not burned the ingredients?

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ANSWER: The inclusion of the ingredients on lists of substances approved for food use by FEMA or FDA indicates that data have been reviewed by scientists who have concluded that the ingredient is suitable for human consumption. In addition, the companies routinely evaluate scientific data on ingredients. It should be noted that many foods and food ingredients are subject to high temperatures during food processing and common forms of cooking, such as frying, baking and broiling, circumstances that are analogous to those undergone by ingredients in a burning cigarette.

29. Isn't it true that the committees which compiled the list of approved tobacco additives in Great Britain and in Germany did not have much information available to them about specific ingredients, but rather conducted a cursory examination?

ANSWER: On the contrary, the reviews were independent and thorough. I would remind you that the Independent Scientific Committee on Smoking and Health in the United Kingdom was established under the Department of Health and Human Services. It is also broadly recognized that the German government has been scrupulous in its review of the ingredients issue. These committees included independent scientists and government representatives. In developing a list of approved substances, they examined the evidence they believed necessary to make an adequate evaluation, and concluded that the ingredients

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were suitable for use in cigarette manufacture. In some cases, the committees had available to them a large body of evidence, including test results. In other instances, a smaller amount of evidence may have been available, particularly for substances typically used only in small quantities. Nevertheless, the review was independent and thorough.

30. What are the large-volume ingredients, why are they used, and what is known about their health effects?

ANSWER: While comment on the identity of any individual ingredient would be inappropriate, they generally have been used in cigarettes for decades and are extensively used in foods. Most of these ingredients serve as casing materials, humectants, or processing aids. Processing aids will remain in the final cigarettes only in trace quantities, if at all. Casing materials smooth and balance the taste of a cigarette, and humectants serve to retain the moisture in cigarettes. A variety of tests have been done to evaluate the health effects of the major ingredients. These include tests by the companies, as well as other work reflected in the published literature. Based on the available information, the companies believe that the addition to cigarettes of the ingredients on the list is not harmful to smokers.

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31. How many known carcinogens are on the list of ingredients which was submitted to HHS?

ANSWER: None of the ingredients on the list is considered a potential human carcinogen by HHS, the International Agency for Research on Cancer (IARC), or other recognized organizations which evaluate the carcinogenic potential of substances.

32. Are natural extracts harmful?

ANSWER: Natural extracts are used in a multitude of foods, drugs, and other products. Criticism of their use in cigarettes is contrary to FDA's approval of such extracts for use in many other products. And a review of the scientific literature does not justify any cause for concern. All substances, natural and synthetic, are toxic at very high levels, but there is no evidence that the small quantities of ingredients used in cigarettes are harmful.

33. Have the cigarette manufacturers ever used cloves, eugenol, or coumarin in their cigarettes?

ANSWER: Because specific ingredients are important trade secrets, the industry will not comment on whether these substances are being or have been used. [Note -- this response will be used for all questions about specific ingredients.]

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34. The HHS report indicates that ingredients such as cloves, eugenol and coumarin are used. Is the industry really using these compounds?

ANSWER: While we cannot comment on the specific ingredients used by United States manufacturers, it is important to note that HHS received submissions not only from Covington and Burling on behalf of the six major United States manufacturers, but from other manufacturers and importers of cigarettes as well.

35. A government scientist referred in an article a few years ago in Mother Jones magazine to an unidentifiable "Compound X" which he had discovered in a cigarette. Does this compound really exist, and if so, what does the industry know about it?

ANSWER: The companies have no information about the specific compound which is referred to but not identified in the Mother Jones article.

36. Why is the industry using Covington and Burling as its spokesperson?

ANSWER: The Federal Cigarette Labeling and Advertising Act allows companies jointly to designate an agent to prepare a combined list of ingredients. This is designed to protect the trade secret status of each company's ingredient information. Covington and Burling assisted the industry in earlier discussions with HHS concerning ingredients, and the companies have asked Covington and Burling to continue that representation.

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37. Isn't it true that you really do not know what effect these ingredients are having on the health of smokers?

ANSWER: The companies have reviewed the scientific literature on ingredients and, where appropriate, they have conducted their own tests to obtain additional scientific evidence. The companies believe that the addition to cigarettes of the ingredients on the list is not harmful to smokers.

38. Don't ingredients simply add to the danger presented by cigarettes?

ANSWER: The industry does not believe that it has been established that cigarette smoking causes disease in smokers, or that the addition to cigarettes of the ingredients is harmful to smokers. Most cigarette ingredients are food or approved for use in food by FDA. The companies have reviewed the extensive scientific literature on ingredients, conducted their own tests where appropriate and concluded that the addition of the ingredients on the list to cigarettes is not harmful.

39. Shouldn't the United States have a list of approved ingredients, as in Great Britain or West Germany?

ANSWER: The Federal Cigarette Labeling and Advertising Act provides HHS with ample authority to review the ingredients in use. Current regulation of ingredients is flexible, in that it permits product innovation and still

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allows HHS to monitor the use of ingredients. We do not believe that any change in this approach is necessary.

40. In light of the nonchalant way in which the cigarette industry has used untested additives in billions of cigarettes every year, isn't it time that ingredients were brought under the aegis of the FDA?

ANSWER: The industry believes very strongly that it has acted in a responsible and scientifically rigorous manner. Moreover, as the recently released report by HHS shows, HHS has the necessary authority to review the use of ingredients. We see no reason to create an additional review mechanism.

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